

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 6-15, 27, 29-66 are pending. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. In particular, the hybridization conditions recited in the claims find support, *inter alia*, at page 6, lines 21-22, of the specification.

35 U.S.C. 112 – Definiteness

Claims 6-15, 33 and 42-46 were rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants traverse.

As regards an alleged discrepancy between enzyme activities and EC nomenclature for such enzymes, the claims are amended for clarity. In particular, the substrate of the enzymatic reaction is recited.

High stringency hybridization conditions are recited in the claims.

Claims 12-14 and 44-45 are amended as the Examiner suggests to clarify that the cells are "isolated" instead of within a living organism.

Claims 15 and 46 are amended as the Examiner suggest to specify "isolating" as part of the claimed process.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

35 U.S.C. 112 – Written Description

The specification must convey with reasonable clarity to persons skilled in the art that applicant was in possession of the claimed invention as of the filing date sought. See *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). But the Patent Office has the initial burden of presenting evidence or a reason why persons of ordinary skill in the art would not have recognized such a description of the claimed invention in the original disclosure. See *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). A

specification need not teach, and preferably omits, what is well known in the art. See *Hybritech v. Monoclonal Antibodies*, 231 USPQ 81, 94 (Fed. Cir. 1986).

Claims 6-15, 33 and 42-46 were rejected under Section 112, first paragraph, as allegedly “failing to comply with the written description requirement.” It was further alleged, “The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Applicants traverse because, for the claims as presently amended, the specification teaches a representative number of species within the claimed genus.

Withdrawal of the written description rejection made under Section 112, first paragraph, is requested because the specification conveys to a person skilled in the art that Applicants were in possession of the claimed invention as of the filing date.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 6-15, 33 and 42-46 were rejected under Section 112, first paragraph, because it was alleged that the specification does not reasonably provide enablement. Applicants traverse because, for the claims as presently amended, undue experimentation is not required given the guidance provided in the specification and the art.

The specification provides sufficient disclosure for the skilled person to practice the invention of amended claim 6 or 42: specific activities of the polypeptides are disclosed on page 13-14 including the Table on page 14. Page 17, line 3, further mentions a “substrate degradation test” to evaluate the activity of putative enzymes encoded by the nucleic acid sequences. More detailed information of the activity of the

claimed polypeptides can be found on page 32, line 29, to page 35, line 14. In particular, Example 3 provides an additional assay for assessing vitamin B12 production. All of this information could be used by the skilled person to determine without undue experimentation whether a polynucleotide would satisfy the requirements of amended claim 6 or 42.

Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested because the specification teaches a person of skill in the art to make and use the claimed invention.

Conclusion

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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